

FACECOTZ (SUNSCREEN) - titanium dioxide, zinc oxide cream
Fallien Cosmeceuticals, LTD.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

FaceCÔTZ (Sunscreen)

DRUG FACTS

Active Ingredient

Titanium Dioxide 8%

Zinc Oxide 3.8%

Purpose

Sunscreen

Sunscreen

Uses:

Helps to prevent and reduce the damaging effects of the sun's Ultraviolet light, including wrinkles and reactions associated with sun damage.

Warnings:

For external use only. Avoid contact with eyes. In case of contact, flush eyes thoroughly. Do not use if sensitive to ingredients. If irritation occurs, discontinue use. If irritation persists, see doctor. Keep this and all medications out of reach of children.

Directions:

Apply before exposure to sunlight. Apply uniformly and completely to all exposed skin areas. Reapply every 2-3 hours and after washing, swimming, sweating, or towel drying for maximum protection.

Other Information: May stain some fabrics

Inactive Ingredients:

Alumina, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG 18/18 Methicone, Methicone, PEG-10 Dimethicone

FACECÔTZ is a sunscreen uniquely formulated to offer sheer, elegant protection with a silky, smooth, matte finish. **FACECÔTZ** offers unparalleled aesthetic elegance while providing superb photoprotective performance. Using our proprietary technology, Fallien has formulated multiple particle sizes of micronized titanium dioxide and zinc oxide into a light, silky texture that dries to a clear, yet matte finish on any complexion. **FACECÔTZ** is paraben, oil and fragrance free, and specially formulated without UV absorbing chemicals to offer unsurpassed, irritant free UVA/UVB light protection.

SPF is not Enough

UVA radiation is consistently the same all day and all year long. Everyone requires daily, year round UVA protection. UVA radiation is reasonable for deep skin damage that results in most of the changes associated with skin aging, such as wrinkling. In addition, the effects of UVA damage are cumulative. Since the SPF number does not define the level of UVA protection, products that utilize both titanium dioxide and zinc oxide, are the best method of assuring full spectrum sun protection, from UVA and UVB radiation.

- **Excellent for Sensitive Skin**
- **Free of "Chemical Sunscreen Filters "**
- **Contains no Parabens**
- **Dries Translucent**
- **Full Spectrum Protection**

Made in U.S.A.

Patented

Manufactured exclusively for
Fallene Ltd.,
West Norriton, PA
Made in USA PATENTED

Principal Display Panel – Carton Label

NDC 58892-346-45

Dermatologist

Recommended for Sensitive Skin

FACE

CŌTZ

Contains Only Titanium & ZincTM

VERY WATER-RESISTANT SUN PROTECTION

UVA-UVB

SPF40

1.5 FL. OZ./44.4 ML

NDC 58892-346-45

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Patented

**Dermatologist
Recommended
for Sensitive Skin**



**CONTAINS ONLY
TITANIUM & ZINC™**

**VERY
WATER-RESISTANT
SUN PROTECTION**

**UVA-UVB
SPF 40**

1.5 FL. OZ./ 44.4 ML

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Made in USA PATENTED



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FACECOTZ (SUNSCREEN)

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-346
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	85.4 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	40.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Aluminum Oxide (UNII: LMI26O6933)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Dimethicone (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-346-45	1 in 1 CARTON		
1		44.4 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2009	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE, PACK

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS

